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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,841	07/03/2001	Valerie L. Gerlach	15966-694 CIP2CON1 (CURA-	1449
30623	7590	05/06/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/898,841	GERLACH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-104 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

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## DETAILED ACTION

### *Claim Objections*

Claims 1 to 104 are objected to as reciting an improper Markush Group.

M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

The different amino acid sequences recited in these claims do not share a common utility that is based upon a shared feature or combination of features lacking from the prior art.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I to XVIII. Claims 1 to 4, 38, 41, 53 to 56, 90 and 93, only in so far as they relate to an isolated polypeptide comprising **one** of the eighteen different amino acid sequences recited therein, classified in class 530, subclass 350. For example, group I only relates to SEQ ID NO:2 whereas group X only relates to SEQ ID NO:23.

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XIX to XXXVI. Claims 5 to 14, 39, 42, 57 to 66, 91 and 94, only in so far as they relate to an isolated nucleic acid encoding a polypeptide comprising one of the eighteen different amino acid sequences recited therein, classified in class 435, subclass 69.1.

XXXVII to LIV. Claims 15 to 17, 40, 43, 67 to 69, 92 and 95, only in so far as they relate to an antibody which binds to a polypeptide having one of the eighteen different amino acid sequences recited therein, classified in class 530, subclass 388.22.

LV to LXXII. Claims 18, 44, 45, 70, 96 and 97, in so far as they are drawn to an immunoassay employing an antibody which binds to a polypeptide comprising any one of the eighteen different acid sequences recited therein, classified in class 436, subclass 536.

LXXIII to XC. Claims 19 to 21, 46, 47, 71 to 73, 98 and 99, in so far as they are drawn to a method of detecting a nucleic acid molecule encoding any one of the eighteen different amino acid sequences recited therein in a sample, classified in class 435, subclass 6.

XCI to CVIII. Claims 22 to 24, 50 to 52, 74 to 76, and 102 to 104, in so far as they are drawn to a binding assay employing a polypeptide comprising any one of the eighteen different acid sequences recited therein, classified in class 436, subclass 501.

CIX to CXXVI. Claims 25 and 77, in so far as they are drawn to a method of treatment by administering a compound of unspecified constitution which

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modulates the activity of a polypeptide comprising any one of the eighteen amino acid sequences recited therein, classification undeterminable.

CXXVII to CXLIV. Claims 26 to 29, 48, 78 to 81, 100 and 101, in so far as they are drawn to a method of treatment by administering a polypeptide comprising any one of the eighteen different amino acid sequences recited therein, classified in class 512, subclass 2.

CXLV to CLXII. Claims 30 to 33 and 82 to 85, in so far as they are drawn to a method of treatment by administering a nucleic acid encoding any one of the eighteen different amino acid sequences recited therein, classified in class 935, subclass 62.

CLXIII to CLXXX. Claims 34 to 37, 49 and 86 to 89, in so far as they are drawn to a method of treatment by administering an antibody which binds to a polypeptide comprising any one of the eighteen different amino acid sequences recited therein, classified in class 424, subclass 139.1.

CLXXXI to CXCVI. Claims 51 and 52, in so far as they are drawn to a method of employing a recombinant cell comprising a recombinant a nucleic acid encoding any one of the eighteen different amino acid sequences recited therein to identify compounds, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because:

The isolated proteins which are inventions I to XVIII, the isolated nucleic acids that are inventions XIX to XXXVI, the antibodies that are inventions XXXVII to LIV, and the compounds employed in the methods of inventions CIX to CXXVI are seventy two

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different chemical compositions each of which can be made and used without the others. Lack of unity is shown by the fact that these seventy two different compositions lack a common utility which is based upon a shared structural feature lacking from the prior art.

The isolated polypeptides that are inventions I to XVIII are related to inventions XCI to CVIII and CXXVII to CXLIV as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the binding assay of inventions LVI to LXVI and the methods of treatment that are inventions CXXVII to CXLIV are materially different because they achieve different objectives by employing different steps.

The isolated nucleic acids that are inventions XIX to XXXVI are related to inventions LXXIII to XC, CXLV to CLXII and CLXXXI to CXCVI as products and processes of use. They are shown to be distinct because the methods of treatment that are inventions CXLV to CLXII, the diagnostic methods of inventions LXXIII to XC and the binding assays of inventions CXI to CLXXXI to CXCVI are materially different because they achieve different objectives by employing different steps.

The antibodies that are inventions XXXVII to LIV are related to inventions XXXIV to XLIV and CLXIII to CLXXX as products and processes of use. They are shown to be distinct because the immunoassay of inventions LV to LXXII and the methods of

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treatment that are inventions CLXIII to CLXXX are materially different because they achieve different objectives by employing different steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

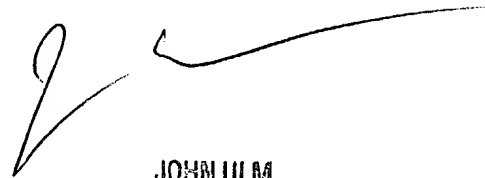
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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